

Although these changes may affect laboratories and PT programs, the impact is not quantifiable and is considered minor compared to the overall beneficial effect of improved laboratory testing accuracy.

- Test requisitions or other written or electronic authorizations for testing must include the patient's sex and age or date of birth as specified now at § 493.1241. We expect a negligible increase in burden or cost because the patient's age or date of birth was required for Pap smears, formerly at § 493.1105(e), and most laboratories are already obtaining the patient's gender, since it is frequently necessary for appropriate test interpretation (as required formerly at § 493.1105(f)). The number of laboratories that have not been requesting the patient's gender and age or date of birth is unknown.

- The laboratory must use a control system capable of detecting reaction inhibition when performing molecular amplification procedures in which inhibition is a significant source of false negative results. This is a recommended guideline for good laboratory practice by several laboratory professional organizations and is now specified at § 493.1256(d)(3)(v). While we are unable to estimate the incidence of reaction inhibition or number of laboratories performing molecular amplification procedures without following the recommended guideline, we expect the number to be small and any increase in burden and/or cost with meeting this new requirement negligible.

- The laboratory must check immunohistochemical stains for positive and negative reactivity each time of use. Although this is an increase from the requirement (formerly at § 493.1259, now at § 493.1273(a)) to check special stains for positive reactivity, we cannot estimate the laboratory impact because we do not know the number of laboratories that perform immunohistochemical stains or how often the staining is performed. We expect this change to affect a small number of laboratories, and the increase in burden and costs will be small.

- In the specialty of clinical cytogenetics, sex determination must be performed by full chromosome analysis. Formerly, in clinical cytogenetics at § 493.1267(a) (now at § 493.1276(c)), full chromosome analysis was only required as a confirmatory test when the laboratory obtained atypical results on X and Y chromatin counts. Several commenters stated that due to the frequency of mosaicism in individuals with sex chromosome aneuploidy, Barr body and "Y" body analysis is no longer considered the standard of practice for

sex determination and should be eliminated from the cytogenetics laboratory test menu. Several laboratory professional organizations consider sex determination by full chromosome analysis the standard for good laboratory practice; therefore, we added this requirement. Although we are unable to estimate the number of cytogenetics laboratories that perform sex determination other than by full chromosome analysis, we expect the number to be small and any increase in burden or cost with meeting this requirement negligible.

- The requirements for the test report (formerly at § 493.1109, now at § 493.1291) must include the patient's name and identification number, or unique patient identifier and identification number; the test report date; and if appropriate, the specimen source. These are standard practices in most laboratories and the impact on burden or cost is expected to be minor.

In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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